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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,979	02/05/2004	Wayne A. Becker	1001.1526101	5206
28/075 7590 08/22/2008 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER				
EREZO, DARWIN P				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/772,979

Applicant(s)

BECKER ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office action is in response to applicant's communication filed on 5/19/08.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

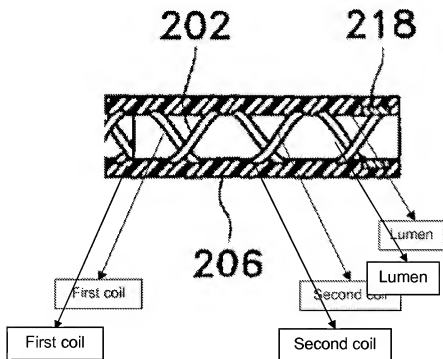
3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1, 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,165,163 to Chien et al. in view of US 6,508,804 to Sarge et al.
 5. (claim 1) The Chien reference discloses a sheath capable of deploying an embolic filter, the sheath comprising:
an elongate shaft **200** having a distal end and a lumen (see Fig. 2);
a coil assembly **202** including:
a first coil defining a lumen, the first coil being wound in a first direction
(see attached portion of Fig. 2),

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a second coil wound in a second direction, the second coil being disposed around the first coil (as seen below, the second coil is disposed around the first coil);

wherein the coil assembly is attached to the distal end **206** of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil (see attached portion of Fig. 2, below).



Chien discloses a dual coil reinforcement of a hollow tube, wherein the first coil and second coil are braided/weaved around each other. Chien fails to teach the second coil being wound about an outer surface of the first coil.

However, Sarge discloses another type of dual coil reinforcement for a hollow tube, wherein a first coil is provided and being wound in a first direction and a second coil is provided and being wound in a second direction, as shown in portion **44** of Figs.

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3-6. Thus, the reinforcement of Sarge is shown to be an equivalent structure known in the art.

Therefore, because these two types of dual coil reinforcement structures were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the dual coil reinforcement of Sarge for the dual coil reinforcement of Chien. Furthermore, it has been held that a simple substitution of known element for another would be obvious to one of ordinary skill in the art since it would provide predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

With regards to the newly added limitation of "the coil assembly is disposed about at least a portion of the distal end of the shaft", it is noted that the term "at least a portion" does not specifically provide any dimension for the distal end. Furthermore, Chien discloses a distal end having a dual coil reinforcement.

(claims 8-10) Chien discloses the first coil and the second coil being made of a metallic ribbon having a rectangular cross-section, as seen in Fig. 9.

(claim 12) Chien discloses the coil assembly having coat layer comprising a polymer (col. 8, lines 28-37).

(claim 13) Chien discloses the coil assembly heat bonded to the shaft (col. 14, lines 51-60). It should also be noted that the claimed limitation is being treated as a product-by-process claim. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited step, only to the structure implied by the

step. Therefore, the process of heating the shaft to the coil assembly does not hold any patentable weight.

(claims 14 and 15) Chien discloses that the first coil and the second coil may be polymer coated (col. 14, lines 36-40).

6. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. in view of Sarge et al., as applied to claim 1 above, and in view of US 5,429,597 to DeMello et al.

(claims 2-4) The modified device of Chien discloses all the limitations of the claims, except for the coils being multifilar. However, DeMello discloses a similar catheter having a shaft that is also reinforced with coils, wherein the coils are multifilar (col. 2, lines 36-41). Thus, the multifilar coil of DeMello is an equivalent structure known in the art. Therefore, since the coil of Chien and the multifilar coil of DeMello were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the multifilar coil of DeMello for the coil of Chien.

(claims 5-7) The modified device of Chien discloses all the limitations of the claims, except for the coil having a circular cross-section. Instead, Chien discloses a rectangular cross-section, as shown in Fig. 9. However, DeMello discloses a similar catheter comprising a shaft having a reinforced coil, wherein the coil is shown to have either a circular cross-section or a rectangular cross-section (col. 3, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the coil of Chien to have a circular cross-section because

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DeMello discloses that a coil having a circular cross-section or a rectangular cross-section are art recognized equivalents and would perform equally as well as a coil having rectangular cross-section. Furthermore, the applicant has not provided any criticality for the coil having a circular cross-section rather than a rectangular cross-section.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. in view of Sarge, et al., as applied to claim 1 above, and in view of US 6,143,013 to Samson et al.

The modified device of Chien discloses all the limitation of the claim, except for the coil assembly having a proximal taper. Instead, Chien appears to disclose a straight shaft without any tapering. However, Samson discloses a similar-type of reinforced catheter, wherein the catheter comprises a coil assembly **206**, and wherein the coil assembly includes a tapering portion along the length of the shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shaft and coil assembly of Chien to have a tapered portion because the shape of the shaft is merely dependent on the intended use of the device. It is well known in the art to have catheters with varying shapes and sizes. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the proximal end to have a tapering since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

8. Claims 16, 23-25, 27-31, 38-40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,873,978 to Ginsburg and in view of Chien et al. and Sarge et al., which is recited above.

(claims 16 and 31) Ginsburg discloses an embolic protection sheath comprising:
an elongate shaft **12** having a distal end and a lumen (see Fig. 2); and
an embolic protection device including an elongate wire **22** and a filter **14**
attached thereto, wherein the wire is disposed at least in part of the shaft lumen (see Fig. 2 or 3).

Ginsburg is silent with regards to the elongate shaft and its distal end comprising a coil assembly; wherein the coil assembly includes a first coil and a second a second coil wound in opposite direction, and wherein the lumen of the shaft is in fluid communication with the lumen of the first coil.

The modified coil reinforcement of Chien, as applied to claim 1, discloses a reinforced catheter capable of delivering an embolic protection device, wherein the catheter includes an elongate shaft **200** having a distal end and a lumen (see Fig. 2); a coil assembly **202** including a first coil defining a lumen, the first coil being wound in a first direction (see attached portion of Fig. 2), a second coil wound in a second direction, the second coil being disposed around the first coil (as seen below, the second coil is disposed around the first coil); and wherein the coil assembly is attached to the distal end **206** of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil (see attached portion of Fig. 2); wherein the second coil is disposed

about an outer surface of the first coil. The reinforced catheter of Chien provides a kink-resistant shaft.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of Chien in the device of Ginsburg because the reinforced catheter of Chien is kink resistant but still flexible enough to move through the vascular system. Being kink resistant would guarantee that the catheter will not collapse.

(claims 23-25 and 38-40) Chien discloses the first coil and the second coil being made of a metallic ribbon having a rectangular cross-section, as seen in Fig. 9.

(claims 27 and 42) Chien discloses the coil assembly having coat layer comprising a polymer (col. 8, lines 28-37).

(claim 28) Chien discloses the coil assembly heat bonded to the shaft (col. 14, lines 51-60). It should also be noted that the claimed limitation is being treated as a product-by-process claim. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited step, only to the structure implied by the step. Therefore, the process of heating the shaft to the coil assembly does not hold any patentable weight.

(claims 29, 30, 43 and 44) Chien discloses that the first coil and the second coil may be polymer coated (col. 14, lines 36-40).

9. Claims 17-22 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ginsburg and Chien et al./Sarge et al., as applied to claims 16 and 31 above, and in view of DeMello et al., as applied to claims 2-7.

(claims 17-19 and 32-34) The above combination of Ginsburg/Chien discloses all the limitations of the claims, except for the coils being multifilar. However, DeMello discloses a similar catheter having a shaft that is also reinforced with coils, wherein the coils are multifilar (col. 2, lines 36-41). Thus, the multifilar coil of DeMello is an equivalent structure known in the art. Therefore, since the coil of Chien and the multifilar coil of DeMello were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the multifilar coil of DeMello for the coil of Chien.

(claims 20-22 and 35-37) The above combination of Ginsburg/Chien discloses all the limitations of the claims, except for the coil having a circular cross-section. Instead, Chien discloses a rectangular cross-section, as shown in Fig. 9. However, DeMello discloses a similar catheter comprising a shaft having a reinforced coil, wherein the coil is shown to have either a circular cross-section or a rectangular cross-section (col. 3, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the coil of Chien to have a circular cross-section because DeMello discloses that a coil having a circular cross-section or a rectangular cross-section are art recognized equivalents and would perform equally as well as a coil having rectangular cross-section. Furthermore, the applicant has not provided any criticality for the coil having a circular cross-section rather than a rectangular cross-section.

10. Claims 26 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ginsburg and Chien et al./Sarge et al., as applied to claims 16 and 31 above, and in view of Samson et al., as applied to claim 11 above.

The above combination of Ginsburg/Chien discloses all the limitation of the claim, except for the coil assembly having a proximal taper. Instead, Chien appears to disclose a straight shaft without any tapering. However, Samson discloses a similar-type of reinforced catheter, wherein the catheter comprises a coil assembly **206**, and wherein the coil assembly includes a tapering portion along the length of the shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shaft and coil assembly of Chien to have a tapered portion because Samson discloses that tapering coil assemblies are known in the art. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the proximal end to have a tapering since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Response to Arguments

11. Applicant's arguments filed 5/19/08 have been fully considered but they are not persuasive.

The applicant main argument throughout the remarks is regarding the Chien/Sarge references. It was argued that Chien does not disclose "a coil assembly [[is]] disposed about at least a portion of the distal end of the shaft". Instead, it was argued that "Chien appears to describe a shaft possibly suitable for use with the coil

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assembly of the pending invention". However, this is not persuasive the invention of claim 1 merely requires that a shaft having a distal end; and a coil assembly, wherein the coil assembly is disposed about at least a portion of the distal end. This is the exact configuration disclosed by Chien and illustrated in the figure provided above. As shown, there is a first and second coil disposed "about a portion of the distal end of the shaft", and wherein the lumen defined by the first coil is in fluid communication with the lumen of the shaft.

It is noted that the figure provided by the applicant in page 9 of the Remarks is NOT the device recited in the claim 1. This figure requires: (a) a coil assembly having a tapered/flared end and a diameter that is larger than the diameter of the shaft; (b) the coil assembly having a proximal end attached to the outer surface of the distal end of the shaft. These limitations are not currently recited in the claimed invention. Instead, the examiner's interpretation of the claim, as shown in the figure provided in this Office action, is the broadest reasonable interpretation of the claimed invention.

It is also noted that the Sarge reference was provided to show that there are several types of dual coil reinforcements for a hollow tube, and that the dual coil reinforcement of Sarge is an art-recognized equivalent to the dual coil reinforcement of Chien.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Primary Examiner, Art Unit 3773